Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the efficacy of radioactive iodide 125 made in Iran in uveal melanoma

Protocol summary

Summary

Purpose: Determining the Efficacy of radioactive Iodide plaques: Inclusion and exclusion keys: All the patients with uveal melanoma not treatable with Ruthenium plaques will include. All the patients with unwillingness to continuing the project, pregnancy, lactation will be excluded from the study. Sample size: 10-15 consecutive patients. the contribution and its time and consequences: After the diagnosis, the iodide plaque will be implanted under the lesion on sclera as soon as it is made and after the predetermined time will be explanted. Then the patient will be followed up in the following months for evaluating any decreasing in the thickness and resorption of subretinal fluid. The stability of the thickness and/or its decreasing is the main outcome of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091929875N1**
Registration date: **2016-10-05, 1395/07/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-10-05, 1395/07/14

Registrant information

Name
Fariba Ghassemi
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Atomic energy agency and Tehran University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of radioactive iodide 125 made in Iran in uveal melanoma

Public title

Using radioactive iodide 125 in uveal melanoma

Purpose

Treatment

Inclusion/Exclusion criteria

INCLUSION: All the patients with uveal melanoma that are not the candidates for ruthenium plaques and un-acception of the enucleation by the patient. Exclusion: Unwillingness of the patient for continuing the study, pregnancy and nursing.

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

2

Groups that have been masked
No information
Sample size
Target sample size: **15**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences ethics committee
Street address
Number 1 building of Tehran University of Medical Sciences, Keshavarz Boulvard, Qods street
City
Tehran
Postal code
Approval date
2016-06-26, 1395/04/06
Ethics committee reference number
IR.TUMS.REC.1395.2742

Health conditions studied

1

Description of health condition studied
Uveal melanoma
ICD-10 code
C69.3
ICD-10 code description
Choroid

Primary outcomes

1

Description
Decrease in the thickness of tumor
Timepoint
At 4 months
Method of measurement
ultrasound and clinical examination

Secondary outcomes

empty

Intervention groups

1

Description
This intervention will be undertaken as implantation of Iodide radioactive plaque under the ocular tumor on sclera, for a measured time, according to the thickness of the tumor. After this period of time, the plaque will be removed and the patient will be followed.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran University of Medical Sciences
Full name of responsible person
Fariba Ghassemi
Street address
Farabi Hospital, South Kargar street, Qazvin Square
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Masoud Younesian
Street address
Farabi Hospital, South Kargar, Qazvin square
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty